To: LaPoma, Jennifer[LaPoma.Jennifer@epa.gov]

Cc: Willard Potter[otto@demaximis.com]; Nace, Charles[Nace.Charles@epa.gov]; Sivak,

Michael[Sivak.Michael@epa.gov]; William Hyatt[william.hyatt@klgates.com]

From: Robert Law

Sent: Mon 10/3/2016 6:27:23 PM
Subject: RE: Revised 17-mile BERA Matters
20160912 Proposed BERA Matters to R2.docx

Jennifer:

As discussed today during our 11:30 teleconference between EPA Region 2 and CPG representatives, the CPG is requesting a short extension for the delivery of the revised draft 17-mile BERA from October 3.

Pursuant to the below e-mails, on September 12, the CPG provided EPA Region 2 with a list of issues related to the revised BERA that the CPG needed EPA's direction on prior to delivery. Region 2 provided its response and directions on September 27. In order to adequately address the EPA's responses to Items 3-6; the CPG is currently making revisions to the Draft BERA that conform with these directions, but given the short timing, is unable to adequately address the directions, review the changes with our client (which, as you know, is comprised of more than 50 companies), and deliver today a revised document that we believe EPA would consider acceptable for approval. The CPG's goal is to deliver the revised draft BERA to EPA Region 2 as soon as possible and no later than October 14.

The CPG believes we are currently on track to deliver the document to EPA Region 2 as early as one week from today.

The CPG appreciates EPA Region 2's consideration in this matter.

Please contact Bill Potter or me.

Thank you.

R/

Rob

Robert Law, Ph.D. de maximis, inc. rlaw@demaximis.com Voice: 908-735-9315 Fax: 908-735-2132

>>> "LaPoma, Jennifer" <LaPoma.Jennifer@epa.gov> 9/27/2016 1:57 PM >>> Rob, As a follow up to the attached document, please see our responses below:

EPA Response to Item 1: Ok, EPA will review the language in the revised draft BERA.

EPA Response to Item 2: The proposal appears consistent with the direction EPA has provided. To reiterate previous discussions, EPA does not consider discussion of EPA's TRVs as "invalid" or "not sound" to be acceptable. The TRVs that are used will provide a bounding estimate and scientific discussion on the difference between the TRVs should be provided.

EPA Response to Item 3: An alternative evaluation of the SQT should not be presented in the BERA as it will not be considered acceptable. A discussion of scientifically relevant concerns related to the SQT, with quantitative interpretation as appropriate, may be presented in the Uncertainty Section of the BERA.

EPA Response to Item 4: EPA expects to see discussion of the two different methods for inorganic compounds that explains whether the comparison yields similar results or yields not similar results. The dietary dose for inorganic compounds would be in the Risk Characterization Section of the BERA. The Uncertainty Section would contain the TRV tissue-based comparison for inorganic compounds and the similarity or differences in the compounds and/or risk levels would be discussed.

EPA Response to Item 5 and 6: The revised draft BERA should clearly state what chemicals of potential concern (COPCs) are and what risk drivers are.

The BERA will identify COPCs in the SLERA portion of the evaluation. Those COPCs are further evaluated in the BERA to identify chemicals that exceed a hazard index of 1 and thus are considered chemicals that contribute to unacceptable risk. Those chemicals that exceed a hazard index of 1 are sometimes referred to as potential chemicals of concern. This list of chemicals are then evaluated to determine if they are site-related and/or similar to background concentrations. The chemicals that are determined to contribute to unacceptable risk that are site-related and greater than background concentrations, are presented at the end of the BERA of chemicals to address for remedial alternatives by the risk manager in the feasibility study.

From: Robert Law [mailto:rlaw@demaximis.com]
Sent: Monday, September 12, 2016 11:12 AM
To: LaPoma, Jennifer <LaPoma.Jennifer@epa.gov>

Cc: Willard Potter <otto@demaximis.com>; Lisa Saban <LisaS@windwardenv.com>; Mike

Johns <MikeJ@windwardenv.com>
Subject: Revised 17-mile BERA Matters

Jennifer:

As we discussed on August 24, the CPG has identified a number of matters in the attached document related to the revised BERA that the CPG is seeking the Region's direction prior to delivery.

Please contact Bill or me with any questions.

Thank you.

R/ Rob Robert Law, Ph.D. de maximis, inc. rlaw@demaximis.com
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